



June 14, 2004

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Re: Docket # 2004Q-0151 Qualified Health Claim (QHC): Soy Protein and Cancer

To Whom It May Concern:

In response to your request, The United Soybean Board would like to provide the following information regarding the health claim petition recently submitted by the Solae Company. This petition proposes a qualified health claim on the association between consumption of soy protein containing foods and the reduced risk of certain cancers.

The American Cancer Society (ACS) estimates that in 2004, 1.3 million new cases of cancer will be diagnosed and greater than 500,000 people will die from cancer-related disease. ACS further states, "There is strong scientific evidence that healthful dietary patterns, in combination with regular physical activity, can reduce cancer risk. Approximately 35 per cent of cancer deaths in the United States may be avoidable through dietary modification."

Today most consumers are aware that food choice has an impact on their daily well-being as well as their long-term health and risk of diseases. However, many do not understand how to construct a healthy diet given the array of choices currently available. Health claims on packages provide consumers with validated evidence of a specific health benefit associated with consumption of a specific food or ingredient.

We believe that The Solae Company's petition is a comprehensive evaluation of the existing scientific research investigating consumption of soy-based foods and the reduced risk of certain types of cancer. The petition extensively reviews 58 epidemiological studies which include 22 studies assessing the role of soyfood consumption on the risk of breast cancer, 10 studies on prostate cancer risk and 30 studies on the risk of cancers of gastrointestinal tract. (Some studies reviewed more than one type of cancer.) This assessment is not unlike other health claims for cancer risk reduction based on epidemiological evidence such as those for limiting dietary fat and increasing intake of fiber-containing grain products, fruits and vegetables.

The Solae Company further conducted meta-analyses on each specific cancer type that allow for a comprehensive view of the data taken together. These meta-analyses resulted in the

following pooled risk estimates for consumption of soy protein-containing foods and:

Cancer	Population	Pooled Risk Estimate (p-value)
Breast Cancer	Women (all ages)	0.78 (p<0.001)
	Post-menopausal Women	0.64 (p<0.005)
Prostate Cancer	Men	0.66 (p<0.001)
Gastro-intestinal Cancer	Men/Women	0.70 (p<0.001)

These pooled estimates indicate significant reductions in the risk of developing these cancers among those who consumed foods containing soy protein.

The level of intake in the petition suggests inclusion of 5.0g of soy protein would qualify food or beverage to carry the claim. This is based on the estimated soy protein consumption of these epidemiological studies and a value found to be associated with reduction in the risk of the stated cancers. The data further support that those consuming the greatest amount of soy protein had the lowest risk of these cancers.

Because health claims provide important and validated information on specific health benefits associated with specific foods and/or ingredients, we believe that this health claim will be of great value to consumers in their efforts to select foods for a healthy diet. We are pleased that the FDA has decided to review The Solae Company's petition and look forward to authorization of the qualified health claim for soy protein containing foods and reduced risk of cancer.

Sincerely,



John Becherer, Chief Executive Officer  
United Soybean Board